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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/894,657	06/28/2001	Jennifer L. Hillman	PF-0421-2 DIV	1636
27904	7590	02/25/2004	EXAMINER	
INCYTE CORPORATION 3160 PORTER DRIVE PALO ALTO, CA 94304			HARRIS, ALANA M	
			ART UNIT	PAPER NUMBER

1642

DATE MAILED: 02/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/894,657

Applicant(s)

HILLMAN ET AL.

Examiner

Alana M. Harris, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 December 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 10, 29-44 and 51 is/are pending in the application.
- 4a) Of the above claim(s) 1, 29, 32, 34, 43, 44 and 51 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10, 30, 31, 33 and 35-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment and Arguments

1. Claims 1, 10, 29-44 and 51 are pending.

Claims 1, 29, 32, 34, 43, 44 and 51, drawn to non-elected inventions are withdrawn from examination.

Claim 52 has been cancelled.

Claims 10, 30, 31, 33 and 35-42 are examined on the merits.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Withdrawn Rejection

Claim Rejections - 35 USC § 112

3. The rejection of claims 10, 30, 31, 33 and 35-42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in light of the amendment to claim 10. Claim 52 has been cancelled.

Maintained Rejections

Claim Rejections - 35 USC § 101/Claim Rejections - 35 USC § 112

4. The rejection of claims 10, 30, 31, 33 and 35-42 under 35 U.S.C. 101 because the claimed invention is not supported by either a substantial asserted utility or a well established utility. Claim 52 has been cancelled.

Applicants have argued these rejections simultaneously. Applicants set forth the utility requirement of section 101 of the Patent Act and suggest that the mere association of the claimed polypeptide with apoptosis and expression in apoptosis-inducible cell line are sufficient utilities under 35 U.S.C. 101, as well as U.S.C. 112, first paragraph. Applicants also submit several papers and a Declaration by Furness in support of meeting the requirements of 35 USC § 101. The Examiner has carefully reviewed all of the submissions of the 4th of December 2003 including the Furness declaration and reconsidered Applicants' remarks. These points of view have been found to be unpersuasive.

The Examiner has presented Applicants with sound scientific reasoning that evidences that predicting protein function based on sequence homology is not as straight forward as Applicants suggest, especially when characterizing an alleged claimed invention. Applicants' arguments appear to be based on the substantial likelihood that if a molecule is well known in the art the claimed molecule with shared sequence homology inherently has well established utility. The fact that the claimed antibody would likely act like a known antibody, or the protein it is to specifically bind would likely be eventually shown to be useful for something does not meet the burden. Utility must be in a readily available form. In *Brenner v. Manson*, 148 U.S.P.Q. 689 (Sup. Ct., 1966), a process of producing a novel compound that was structurally analogous to other compounds which were known to possess anti-cancer activity was

alleged to be useful because the compound produced thereby was potentially useful as an anti-tumor agent in the absence of evidence supporting this utility. The court expressed the opinion that all chemical compounds are "useful" to the chemical arts when this term is given its broadest interpretation. However, the court held that this broad interpretation was not the intended definition of "useful" as it appears in 35 U.S.C. § 101, which requires that an invention must have either an immediately obvious or fully disclosed "real world" utility. Until some actual and specific activity can be attributed to the protein designated as SEQ ID NO: 5 or the antibody that binds it, the claimed invention is incomplete.

Applicants mention drug discovery and toxicology testing as practical uses for the claimed invention, see page 13 of the Remarks. Applicants refer to the Furness Declaration, the specification of the instant application regarding assessing drug toxicity and 2-D PAGE. However, examination of the specification shows clearly that each of these purported utilities is merely use for further research and characterization of SEQ ID NO: 5; discovery of diseases with which the sequences may be associated, or conditions under which one would want or not want to affect expression of such would constitute a part of the invention itself. All the specification as originally filed provides is a wish to know and an invitation to experiment.

Accordingly, the rejection of claims 10, 30, 31, 33 and 35-42 under 35 U.S.C. 112, first paragraph is maintained. Specifically, since the claimed invention is not supported by either a specific asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

5. The rejection of claims 10, 30, 31, 33 and 35-42 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the

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inventor(s), at the time the application was filed, had possession of the claimed invention is maintained. Claim 52 has been cancelled.

Applicants aver the claims have been amended and the this rejection should be withdrawn based on the claim amendment. This point of view has been considered and found to be unpersuasive.

While Applicants have amended claim 10 it reads on any antibody which specifically binds to a polypeptide of SEQ ID NO: 5. The claim continues to embrace fragments of SEQ ID NO: 2, thus a plethora of antibodies that are to bind SEQ ID NO: 5. These antibodies possibly bind a small number of amino acid residues that is less than the 469 amino acids of SEQ ID NO: 5. Hence the claims are drawn to antibodies that bind amino acid residues that minimally contain only portions of SEQ ID NO: 5. Thus, the claims are drawn to a large genus of molecules. Accordingly, the rejection is maintained.

Claim Rejections - 35 USC § 102

6. The rejection of claims 10, 35 and 36 under 35 U.S.C. 102(a) as being anticipated by Matsushashi et al. (Research Communications in Biochemistry and Cell & Molecular Biology 1(1): 109-120, 1997) is maintained. Claim 52 has been cancelled.

Applicants have submitted Exhibit E, which allegedly "...demonstrates the date of invention of SEQ ID NO: 5 ...was at least as early as 16 October 1996.", Remarks, page 25. Applicants submit that this reference antedates the anticipatory art. The Examiner has reviewed the Exhibit and Remarks and they have been found unpersuasive.

The Examiner has reviewed the one sheet labeled Exhibit E and it does not set forth the sequence in question. There is no amino acid listing or any other pertinent information on the sheet that clearly establishes that this citing of a clone ID and project ID verifies Applicants' possession on the sequence prior to Matsushashi. Matsushashi continues to disclose an antibody specific to a polypeptide of SEQ ID NO: 5 as documented in the First Action on the Merits (FAOM) mailed July 1, 2003. The rejection is maintained.

Claim Rejections - 35 USC § 103

7. The rejection of claims 10, 35, 36 38 and 39 under 35 U.S.C. 103(a) as being unpatentable over Matsushashi et al. (Research Communications in Biochemistry and Cell & Molecular Biology 1(1): 109-120, 1997), in view of Campbell (Ailsa M.

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(Laboratory Techniques in Biochemistry and Molecular Biology 13:1-32, 1984) is maintained. Claim 52 has been cancelled.

Applicants argue that the claim has been amended, therefore as currently pending the combination of any of the cited references under 35 U.S.C. 103(a) is improper. This argument has been considered but found unpersuasive.

As set forth in the FAOM Matsushashi teaches a polypeptide of SEQ ID NO: 5 and Campbell teaches a strategy to generate monoclonal antibodies. One of ordinary skill in the art at the time of the claimed invention would have been motivated to produce antibodies to SEQ ID NO: 5 because "[i]t is customary now for any group working on a macromolecule to both clone the genes coding for it and make monoclonal antibodies to it (sometimes without a clear objective for their application).", see Campbell, page 29, Section 1.3.4.

8. The rejection of claims 10, 30, 35 and 36 under 35 U.S.C. 103(a) as being unpatentable over Matsushashi et al. (Research Communications in Biochemistry and Cell & Molecular Biology 1(1): 109-120, 1997), and in view of Bird et al. (Science 242:423-242, 1988) is maintained. Claim 52 has been cancelled.

Applicants argue that Exhibit E antedates the anticipatory reference set forth in the 102(a) rejection. The Examiner has reviewed the Exhibit and the information has been found to be unpersuasive.

The teachings of Matsushashi have been presented in the 102(a) rejection. The 102(a) rejection has been maintained. Exhibit E submitted by Applicants' does not

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contain essential information verifying it antedates the primary reference, Matsuhashi. Accordingly, the 103 rejection with Matsuhasi as the primary reference is maintained.

9. The rejection of claims 10, 35, 36, 41 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Matsuhashi et al. (Research Communications in Biochemistry and Cell & Molecular Biology 1(1): 109-120, 1997), in view of Huse et al. (Science 246:1275-1281, December 8, 1989) is maintained. Claim 52 has been cancelled.

Applicants argue that Exhibit E antedates the anticipatory reference set forth in the 102(a) rejection. The Examiner has reviewed the Exhibit and the information has been found to be unpersuasive.

The teachings of Matsuhashi have been presented in the 102(a) rejection. The 102(a) rejection has been maintained. Exhibit E submitted by Applicants' does not contain essential information verifying it antedates the primary reference, Matsuhashi. Accordingly, the 103 rejection with Matsuhashi as the primary reference is maintained.

10. The rejection of claims 10, 30, 31, 33, 35 and 36 under 35 U.S.C. 103(a) as being unpatentable over Matsuhashi et al. (Research Communications in Biochemistry and Cell & Molecular Biology 1(1): 109-120, 1997), in view of U.S. Patent number 6,180,370 (filed June 7, 1995) is maintained. Claim 52 has been cancelled.

Applicants argue that Exhibit E antedates the anticipatory reference set forth in the 102(a) rejection. The Examiner has reviewed the Exhibit and the information has been found to be unpersuasive.

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The teachings of Matsuhashi have been presented in the 102(a) rejection. The 102(a) rejection has been maintained. Exhibit E submitted by Applicants' does not contain essential information verifying it antedates the primary reference, Matsuhashi. Accordingly, the 103 rejection with Matsuhasi as the primary reference is maintained.

11. The rejection of claims 10, 31 and 35-37 under 35 U.S.C. 103(a) as being unpatentable over Matsuhashi et al. (Research Communications in Biochemistry and Cell & Molecular Biology 1(1): 109-120, 1997), in view of Harlow and Lane (Antibodies, A Laboratory Manual, Cold Spring Harbor Laboratory, 1988) is maintained.

Applicants argue that Exhibit E antedates the anticipatory reference set forth in the 102(a) rejection. The Examiner has reviewed the Exhibit and the information has been found to be unpersuasive.

The teachings of Matsuhashi have been presented in the 102(a) rejection. The 102(a) rejection has been maintained. Exhibit E submitted by Applicants' does not contain essential information verifying it antedates the primary reference, Matsuhashi. Accordingly, the 103 rejection with Matsuhasi as the primary reference is maintained.

12. The rejection of claims 10, 38 and 39 under 35 U.S.C. 103(a) as being unpatentable over Onishi et al. (Biochem. Biophys. Res. Commun. 228:7-13, 1996/ IDS reference #8), in view of Campbell (Ailsa M. (Laboratory Techniques in Biochemistry and Molecular Biology 13:1-32, 1984) is maintained.

Applicants argue that the claim has been amended, therefore as currently pending the combination of any of the cited references under 35 U.S.C. 103(a) is improper. This argument has been considered but found unpersuasive.

As set forth in the FAOM Matsuhashi teaches a polypeptide of SEQ ID NO: 5 and Campbell teaches a strategy to generate monoclonal antibodies. One of ordinary skill in the art at the time of the claimed invention would have been motivated to produce antibodies to SEQ ID NO: 5 because "[i]t is customary now for any group working on a macromolecule to both clone the genes coding for it and make monoclonal antibodies to it (sometimes without a clear objective for their application).", see Campbell, page 29, Section 1.3.4.

13. The rejection of claims 10, 38 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shibahara et al. (Gene 166: 297-301, 1995/ IDS reference #7),

in view of Campbell, Ailsa M. (Laboratory Techniques in Biochemistry and Molecular Biology 13:1-32, 1984) is maintained. Claim 52 has been cancelled.

Applicants argue that the claim has been amended, therefore as currently pending the combination of any of the cited references under 35 U.S.C. 103(a) is improper. This argument has been considered but found unpersuasive.

As set forth in the FAOM Matsushita teaches a polypeptide of SEQ ID NO: 5 and Campbell teaches a strategy to generate monoclonal antibodies. One of ordinary skill in the art at the time of the claimed invention would have been motivated to produce antibodies to SEQ ID NO: 5 because "[i]t is customary now for any group working on a macromolecule to both clone the genes coding for it and make monoclonal antibodies to it (sometimes without a clear objective for their application).", see Campbell, page 29, Section 1.3.4.

14. The rejection of claims 10, 30, 38 and 39 under 35 U.S.C. 103(a) as being unpatentable over Onishi et al. (Biochem. Biophys. Res. Commun. 228:7-13, 1996/ IDS reference #8) or Shibahara et al. (Gene 166: 297-301, 1995/ IDS reference #7) in view of Campbell, Ailsa M. (Laboratory Techniques in Biochemistry and Molecular Biology 13:1-32, 1984) as applied to claims 10, 38, 39 and 52 above, and further in view of Bird et al. (Science 242:423-442, 1988) is maintained. Claim 52 has been cancelled.

Applicants argue that the claim has been amended, therefore as currently pending the combination of any of the cited references under 35 U.S.C. 103(a) is improper. This argument has been considered but found unpersuasive.

For the reasons set forth above and of record the rejection is maintained.

15. The rejection of claims 10, 38, 39, 41 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Onishi et al. (Biochem. Biophys. Res. Commun. 228:7-13, 1996/ IDS reference #8) or Shibahara et al. (Gene 166: 297-301, 1995/ IDS reference #7) in view of Campbell , Ailsa M. (Laboratory Techniques in Biochemistry and Molecular Biology 13:1-32, 1984) as applied to claims 10, 38, 39 and 52 above, and further in view of Huse et al. (Science 246:1275-1281, December 8, 1989) is maintained. Claim 52 has been cancelled.

Applicants argue that the claim has been amended, therefore as currently pending the combination of any of the cited references under 35 U.S.C. 103(a) is improper. This argument has been considered but found unpersuasive.

For the reasons set forth above and of record the rejection is maintained.

16. The rejection of claims 10, 30, 31, 33, 38 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Onishi et al. (Biochem. Biophys. Res. Commun. 228:7-13, 1996/ IDS reference #8) or Shibahara et al. (Gene 166: 297-301, 1995/ IDS reference #7) in view of Campbell , Ailsa M. (Laboratory Techniques in Biochemistry and Molecular Biology 13:1-32, 1984) as applied to claims 10, 38, 39 and 52 above, and further in view of U.S. Patent number 6,180,370 (filed June 7, 1995) is maintained. Claim 52 has been cancelled.

Applicants argue that the claim has been amended, therefore as currently pending the combination of any of the cited references under 35 U.S.C. 103(a) is improper. This argument has been considered but found unpersuasive.

For the reasons set forth above and of record the rejection is maintained.

17. The rejection of claims 10 and 35-40 under 35 U.S.C. 103(a) as being unpatentable over Onishi et al. (Biochem. Biophys. Res. Commun. 228:7-13, 1996/ IDS reference #8) or Shibahara et al. (Gene 166: 297-301, 1995/ IDS reference #7) in view of Campbell, Ailsa M. (Laboratory Techniques in Biochemistry and Molecular Biology 13:1-32, 1984) as applied to claims 10, 38, 39 and 52 above, and further in view of Harlow and Lane (Antibodies, A Laboratory Manual, Cold Spring Harbor Laboratory, 1988) is maintained.

Applicants argue that the claim has been amended, therefore as currently pending the combination of any of the cited references under 35 U.S.C. 103(a) is improper. This argument has been considered but found unpersuasive.

For the reasons set forth above and of record the rejection is maintained.

Conclusion

18. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (571)272-0831. The examiner can normally be reached on 7:00 am to 4:30 pm, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne "Bonnie" Eyler, Ph.D. can be reached on (571)272-0871. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ALANA M. HARRIS, PH.D.

PRIMARY EXAMINER



Alana M. Harris, Ph.D.

23 February 2004